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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/886,241	06/21/2001	Susana Salceda	DEX-0209	5811

26259 7590 01/20/2004

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EXAMINER

HARRIS, ALANA M

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 01/20/2004

12

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/886,241

Applicant(s)

SALCEDA ET AL.

Examiner

Alana M. Harris, Ph.D.

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 28 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 3-7 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 3-7 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Response to Arguments and Amendments***

1. Claims 3-7 are pending.  
Claims 1, 2 and 8-15 have been cancelled.  
Claims 3-7 have been amended.  
Claims 3-7 are examined on the merits.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Withdrawn Rejection***

#### ***Claim Rejections - 35 USC § 112***

3. The rejection of claims 3-7 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is withdrawn in light of the claim amendments.
4. The rejection of claims 3-7 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention is withdrawn.

Art Unit: 1642

5. The rejection of claims 3-7 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in light of the claim amendments.

***Claim Rejections - 35 USC § 101***

6. The rejection of claims 3-7 under 35 U.S.C. 101 because the claimed invention is not supported by either a specific, substantial, credible or asserted utility or a well established utility is withdrawn.

***New Grounds of Rejection***

***Claim Rejections - 35 USC § 112***

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 3-7 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for determining the levels of expression of SEQ ID NO: 4, does not reasonably provide enablement for determining the level of the gene itself. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Applicants' claims are broadly drawn to the detection of a breast specific gene (BSG) in cells, tissues or bodily fluids in a patient and comparing the determined levels

Art Unit: 1642

of said gene with levels of BSG in cells, tissues or bodily fluids from a normal human control, wherein a change in determined levels of BSG in said patient versus normal human control is associated with the presence of breast cancer. Applicants' specification supports the comparison of expression levels of SEQ ID NO: 4 and not to levels of the actual gene. In the absence of sufficient guidance and/or working examples concerning the use the claimed methodology one skilled in the art can not practice the broadly claimed invention with a reasonable expectation of success and without undue experimentation.

9. Claims 3-7 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for diagnosing the presence of breast cancer in a patient comprising determining levels of a breast specific polynucleotide designated as SEQ ID NO: 4 (or breast specific gene, BSG: sqmam042) in cells, tissue or bodily fluids in a patient and comparing the determined levels of a polynucleotide comprising SEQ ID NO: 4 or a polynucleotide encoding the same polypeptide in cells, tissue or bodily fluids from a normal human control, wherein a change in determined levels of a BSG polynucleotide comprising SEQ ID NO: 4 or a polynucleotide encoding the same polypeptide as SEQ ID NO: 4 in said patient versus normal human control is associated with presence of breast cancer, does not reasonably provide enablement for methods of diagnosing metastases, staging and monitoring changes in gastrointestinal cancer. The specification does not enable any person skilled in the art to which it

Art Unit: 1642

pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Applicants' remarks received as Paper number 11, section III attests to the sensitivity of the BSG marker, SEQ ID NO: 4 as a unique or molecular marker for breast cancer. The specification does set forth enabling disclosure supporting the occurrence of SEQ ID NO: 4 and its overexpression in breast samples, which is interpreted as diagnostic of breast cancer. This evidence is indicative of SEQ ID NO: 4 being a tumor marker for breast cancer. However, the specification does not support the use of SEQ ID NO: 4 in methods of diagnosing metastases, staging and monitoring gastrointestinal cancer. There is no objective evidence in the specification that SEQ ID NO: 4, mRNA corresponding to SEQ ID NO: 4 or the protein expressed from the polynucleotide would be useful as a marker of metastatic breast cancer. It is well known in the art that metastatic cancer cells have altered patterns of gene expression in comparison with the non-metastatic precursor cancer cell. For instance, metastatic breast cancer cells are negative for E-cadherin expression, while normal breast cells and non-invasive breast cells are positive (Oka et al, Cancer Research, 1993, vol. 53, pp. 1696-1701). Uteroglobin is another example of a gene product, which is expressed in a primary tumor but not in metastatic cells released from said tumor (Weeraratna et al, Clinical Cancer Research, 1997, Vol. 3, pp. 2295-2300). These references demonstrate the lack of correlation between gene expression in a primary tumor versus metastatic cells released from said primary tumor. Therefore, it cannot be predicted that the polynucleotides effective in the diagnosis of breast cancer would be expressed or

Art Unit: 1642

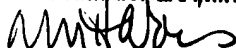
effective in diagnosing metastatic breast cancer and consequently useful in the monitoring and staging the said cancer. The specification does not provide sufficient guidance and direction to implement SEQ ID NO: 4 and its corresponding protein in methods of diagnosing metastases, monitoring and staging breast cancer.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (703) 306-5880. The examiner can normally be reached on 7:00 am to 4:30 pm, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D. can be reached on (703) 308-3995. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4315.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0196.

**ALANA M. HARRIS, PH.D.**  
**PRIMARY EXAMINER**



Alana M. Harris, Ph.D.  
12 January 2004